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REVIEW PROTOCOL

Validity evidence of national early warning score 2: a scoping review protocol

Evidências de validade do *National Early Warning Score 2*: protocolo de revisão de escopo

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ABSTRACT

Objective: To map the scientific literature on the performance of the National Early Warning Score 2 (NEWS2) in recognizing clinical deterioration in patients in pre-hospital and hospital settings. **Method:** This scoping review protocol is developed by the Joanna Briggs Institute (JBI) guidelines and follows the Preferred Reporting Items for Systematic Reviews and Meta-Analyses Extension for Scoping Reviews (PRISMA-ScR). The review will include full-text original articles and grey literature without temporal or language restrictions. The search strategy will be implemented across databases such as MEDLINE, Embase, Scopus, LILACS, Web of Science, and grey literature sources. Titles, abstracts, and full texts, as well as the selection of records and data extraction, will be independently assessed by two reviewers, with blinding maintained throughout all stages. Any disagreements will be resolved by a third reviewer. Reference lists of included studies will be examined to identify studies not captured in the initial search and used as additional sources. Identified records will be grouped and loaded into the Rayyan management system for duplicate removal and final selection. Extracted data will be categorized, summarized, and presented in tables, charts, maps, and narrative summaries.
Descriptors: Early Warning Score; Validation Study; Clinical Deterioration.

RESUMO

Objetivo: mapear as produções científicas sobre o desempenho do *National Early Warning Score* (NEWS *2*) no reconhecimento da deterioração clínica em pacientes atendidos em unidades pré-hospitalares e hospitalares. **Método:** Este é um protocolo de revisão de escopo elaborado em conformidade as diretrizes do *Joanna Briggs Institute* (JBI), seguindo o *Preferred Reporting Items for Systematic Reviews and Meta-Analyses* (PRISMA-ScR). Serão incluídos artigos originais, disponíveis na integra, assim como literatura cinza, sem delimitação temporal e de idioma. A estratégia de busca será executada nas bases MEDLINE, Lilacs, *Embase*, *Scopus*, *Web of Science* e literatura cinza. Os títulos, resumos, textos completos, seleção dos registros e extração dos dados, serão avaliados por dois revisores independentes preservando o cegamento em todas as etapas, e um terceiro revisor solucionará possíveis discordâncias. As listas de referências dos estudos incluídos serão analisadas a fim de identificar estudos perdidos na pesquisa, e em seguida serão utilizados como fontes adicionais. Os registros identificados serão agrupados e carregados no sistema de gerenciamento *Rayyan* para remoção de duplicatas e seleção final dos registros. Os dados extraídos serão categorizados e sumarizados, e apresentados sob a forma de tabelas, gráficos, mapas e resumos narrativos.
Descritores: Escore de Alerta Precoce; Estudo de Validação; Deterioração Clínica.

INTRODUCTION

Clinical deterioration is a state of hemodynamic instability characterized by physiologic decompensation, which in clinical practice can be recognized by changes in vital signs and organ dysfunction[1,2]. Studies indicate that due to its dynamic nature, clinical deterioration can be

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identified by events such as cardiorespiratory arrest, unplanned admission to the intensive care unit (ICU), and, in its most severe stage, hospital death. Therefore, monitoring vital signs and detecting neurological, respiratory and/or cardiovascular disturbances have become crucial for early assessment, prognosis, and patient survival[1-6].

Several early warning scores have been developed to detect early clinical deterioration based on patients' vital signs[7], examples include the National Early Warning Score (NEWS)[8-10] and its most recent version, the National Early Warning Score 2 (NEWS2), developed in the United Kingdom[11,12]. Recently, NEWS2 has undergone cross-cultural adaptation to the Brazilian context[13].

Historically, NEWS2 has undergone a validation process in various countries worldwide, focusing primarily on comparisons with other measures[14–16].

The validity of an instrument is considered to be the accumulation of evidence that allows its interpretation based on a sound and consistent theory. In other words, understanding the validity evidence of an instrument depends on its ability to measure the phenomenon it is intended to measure[17]. Thus, the validation process reveals the strength of the instrument and how well the existing theory can support the empirical evidence generated in different contexts.

In this step, a preliminary search was conducted in April 2023 using the descriptors "National Early Warning Score 2," "NEWS 2," and "Validation Study" on the databases MEDLINE/PubMed, JBI Manual for Evidence Synthesis, and the Cochrane Database of Systematic Reviews. Review protocols were also searched in PROSPERO and the Open Science Framework (OSF). No recent or ongoing systematic or scoping reviews focusing on the analysis of evidence for the validity of NEWS2 in prehospital and hospital settings were identified.

This scoping review is relevant as it aims to understand the validation process of NEWS2 and to support new validation studies of this score in various contexts by analyzing its applicability, performance, and effectiveness. Additionally, the review will contribute to identifying limitations and gaps, expanding knowledge on clinical instrument validation techniques, and enhancing the scientific foundation and state of the art on the investigated topic. It is noteworthy that, for this scoping review, clinical deterioration was defined as the occurrence of at least one of the following events: cardiorespiratory arrest, admission to the Intensive Care Unit, and hospital death.

This scoping review's objective is to map the scientific literature on NEWS2's performance in recognizing clinical deterioration in patients treated in pre-hospital and hospital settings.

Review question

To guide the search for studies a review question was formulated using the PCC acronym P- Population; C- Context; C- Concept, defined as follows: P- Not specified; C- National Early Warning Score 2; C- Validity of National Early Warning Score 2. The research question for the study is: "What is the validity of evidence of NEWS2 as a measurement instrument for clinical deterioration in patients treated in pre-hospital and hospital settings?".

Inclusion criteria

Population

Patients over 16 years of age of both sexes. The population will not be specified in the search strategy to broaden the scope of retrieved articles. Review review authors will include only articles based on the inclusion criteria during data selection.

Concept

This scoping review will consider studies that address NEWS2 in various contexts, both in pre-hospital and hospital settings and applied to different populations.

Context

Studies related to the validity of NEWS2 in recognizing clinical deterioration in patients hospitalized in wards, treated in emergency departments, and attended by pre-hospital services will be included. Clinical deterioration is defined as the occurrence of the following outcomes: cardiorespiratory arrest, unplanned ICU admission, and death.

Types of sources

The scoping review will include evidence sources such as quantitative studies and full-text articles from primary studies published in journals indexed in major health-related databases without temporal or language limits and without restriction on study design. Grey literature, in-

cluding reports available on official websites, theses, dissertations, and preprint articles, will also be included. Review articles, letters to the editor, and opinion articles will be excluded.

METHOD

This is a scoping review protocol developed by the Joanna Briggs Institute (JBI) manual recommendations for evidence synthesis[18]. The Preferred Reporting Items for Systematic Reviews and Meta-Analyses—Extension for Scoping Reviews (PRISMA-ScR) will be used[19]. The protocol is registered on the OSF platform and is available at DOI: 10.17605/osf.io/3nvcp.

Search strategy

The search strategy for this scoping review will not restrict the publication year or language. The final stage will involve three reviewers aiming to locate published and unpublished primary studies through a four-step search process.

Step 1

A limited search will be conducted in the MEDLINE/PubMed and Virtual Health Library (VHL) databases to identify articles on the topic. From this initial search, descriptors and keywords will be combined with the words contained in the articles' titles and abstracts to construct a comprehensive search strategy for MEDLINE/PubMed (Figure 1).

Stage 2

The search strategy will be applied to MEDLINE/PubMed and adapted for the Embase (Elsevier), Scopus (Elsevier), Web of Science (Clarivate), and LILACS (Virtual Health Library) databases.

Stage 3

Articles will be retrieved from the reference lists of the included studies to identify studies missed in the initial search. These studies will be used as additional sources. Reviewers will perform a sensitivity analysis of the strategy to ensure that no significant literature on the topic was overlooked in the initial strategy.

Stage 4

A search will be conducted in grey literature, including the Thesis and Dissertation Database of the CAPES Portal, Cybertesis, Google Scholar, Web of Science, SciELO Preprints, MEDRIXV, and reports on official websites.

Selection of study/source of evidence

After the search, all identified records will be grouped and loaded into the Rayyan management system, where duplicate records will be removed. Titles and abstracts are screened by two independent reviewers according to the study inclusion criteria, with blinding maintained through the Rayyan tool during this phase. A third reviewer will resolve any disagreements regarding study selection.

Subsequently, the full texts of the selected articles will be read by two independent reviewers in a blinded manner, adhering to the inclusion criteria. Full-text articles not meeting the inclusion criteria will be quantified and reported with the reason for exclusion. A third reviewer will resolve disagreements between reviewers during the selection phase.

The search strategy's results will be presented according to the PRISMA-ScR, which will also serve as a writing guide for the final report[20].

Data extraction

Data will be extracted by two reviewers using an extraction tool built in Excel for Windows 10.0, adapted from the JBI instrument to meet the objectives of this review. The tool will include the following categories: title, author, journal, year of publication, country of origin, language, objective, population, sample size, inclusion and exclusion criteria, study location, study design, data collection period, type of validation, primary outcome, secondary outcome, statistical test, measurement instrument for comparison, results, and study limitations (Figure 2).

A pilot test will be conducted to evaluate the extraction tool using a sample of four articles reviewed by two independent reviewers. This test aims to assess the feasibility, information agreement, tool quality, and the need for modifications and adjustments. Any modifications will be detailed in the scoping review during the data extraction process, and a third reviewer will resolve any disagreements. For missing or additional data, the authors of eligible articles will be contacted to provide the necessary information for the assessment.

Data analysis and presentation

The results of this scoping review will be categorized and summarized using frequency counts and presented as tables, charts, maps, and narrative summaries. The evidence found in the included studies and a detailed description of the results will address the review's objective and the research question proposed in the study. All authors involved in this review will conduct data analysis.

Figure 1 – Search strategy. Feira de Santana, BA, Brazil, 2023

SEARCH STRAGTEGY	
Database: MEDLINE (PubMed)	Recovered results: 1348
("EARLY WARNING SCORE"[MESH] OR (EARLY WARNING SCORES) OR (SCORE, EARLY WARNING) OR (SCORES, EARLY WARNING) OR (WARNING SCORES, EARLY) OR (NATIONAL EARLY WARNING SCORE 2) OR (NEWS2)) AND ("VALIDATION STUDY" [PUBLICATION TYPE] OR (VALIDATION STUDIES) OR "VALIDATION STUDIES AS TOPIC"[MESH] OR (VALIDATION STUDIES AS TOPIC) OR "ROC CURVE"[MESH] OR (CURVE, ROC) OR (CURVES, ROC) OR (ROC CURVES) OR (ANALYSIS, ROC) OR (ANALYSES, ROC) OR (ROC ANALYSES) OR (ROC ANALYSIS) OR (RECEIVER OPERATING CHARACTERISTIC) OR (CHARACTERISTIC, RECEIVER OPERATING) OR (CHARACTERISTICS, RECEIVER OPERATING) OR (RECEIVER OPERATING CHARACTERISTICS) OR "SENSITIVITY AND SPECIFICITY"[MESH] OR (SPECIFICITY AND SENSITIVITY) OR (SENSITIVITY) OR (SPECIFICITY) OR "DATA ACCURACY"[MESH] OR (ACCURACIES, DATA) OR (ACCURACY, DATA) OR (DATA ACCURACIES) OR (DATA QUALITY) OR (DATA QUALITIES) OR (QUALITIES, DATA) OR (QUALITY, DATA) OR "REPRODUCIBILITY OF RESULTS"[MESH] OR (REPRODUCIBILITY OF FINDINGS) OR (REPRODUCIBILITY OF RESULT) OR (OF RESULT, REPRODUCIBILITY) OR (OF RESULTS, REPRODUCIBILITY) OR (RESULT, REPRODUCIBILITY OF) OR (RESULTS, REPRODUCIBILITY OF) OR (REPRODUCIBILITY OF FINDING) OR (FINDING REPRODUCIBILITIES) OR (FINDING REPRODUCIBILITY) OR (RELIABILITY OF RESULTS) OR (RELIABILITY OF RESULT) OR (RESULT RELIABILITIES) OR (RESULT RELIABILITY) OR (RELIABILITY (EPIDEMIOLOGY)) OR (VALIDITY (EPIDEMIOLOGY)) OR (VALIDITY OF RESULTS) OR (VALIDITY OF RESULT) OR (RESULT VALIDITIES) OR (RESULT VALIDITY) OR (FACE VALIDITY) OR (VALIDITY, FACE) OR (RELIABILITY AND VALIDITY) OR (VALIDITY AND RELIABILITY) OR (TEST-RETEST RELIABILITY) OR (RELIABILITIES, TEST-RETEST) OR (RELIABILITY, TEST-RETEST) OR (TEST RETEST RELIABILITY))	

Figure 2 – Data extraction tool. Feira de Santana, BA, Brazil, 2023

DATA EXTRACTION TOOL					
IDENTIFICATION OF THE STUDY					
Title	Author	Journal	Year	Country	Language
AIM OF THE STUDY					
METHODOLOGY					
Population (age, sex)	Sample size	Inclusion criteria	Place of study	Study design	Data collection period
DATA ANALYSIS					
Type of validation	Primary outcome	Secondary outcome	Statistical test	Measurement instrument for comparison	
RESULTS					
LIMITATIONS OF THE STUDY					

Source: JBI Manual for Evidence Synthesis, adapted from Aromataris and Munn, 2020

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